

REMARKS

The outstanding Office Action of March 17, 2009 rejects Claim 17 under 35 U.S.C. Sections 101, 103 and 112.

Applicant sincerely appreciates Examiner Rines' thorough and

5 thoughtful review and critique of Claim 17. Taking into account the Examiner's comments, the Application has been amended in response to the Examiner's comments and for the reasons set forth below is now believed to be in condition for allowance.

Specifically, newly submitted independent Claim 18, Claim 17 in
10 rewritten form, defines a classification and management system for patients with lower extremity arterial occlusive disease. Independent Claim 18 defines the system as comprising the number of steps implemented by state of the art computers and CPUs over a network interconnecting a number of remote locations or facilities to treat patients at risk of complications of arterial
15 occlusive disease.

Therefore, Examiner Rines is requested to reconsider the 101 and 112 rejections.

The accompanying paper entitled **SOLUTIONS FOR SAGE COMPANY, A MEMBER OF THE GOODMAN GROUP**, dated November 20 1999, shows that Applicant's invention clearly predates the reference to Crutchfield.

Accordingly, Examiner Rines is requested to reconsider his 103 rejection.

In view of the amendments contained herein and the discussion in
25 support thereof, allowance of this application is respectfully requested.

Attached is a complete listing of all claims in ascending numerical order. Each claim has been provided with the proper status identifier.

Notwithstanding, in the event that this response does not completely and fully address the matters and issues set forth in the outstanding Office
30 Action, Examiner Rines is invited to contact Applicant's attorney by telephone in order to expeditiously conclude this prosecution.

Respectfully submitted,



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**SOLUTIONS FOR SAGE COMPANY
A MEMBER OF THE GOODMAN GROUP**

**PREPARED FOR:
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Director of Operations
Senior Living and Health Care**

TRI-MED MANAGEMENT, INC.

November 1999

OVERVIEW

Following meetings with Christopher J. Adams, Director of Operations for the Sage Company and upon receipt of the data requested Tri-Med Management, Inc. (TMM) has completed its review and prepared the following proposal.

TMM's Total Quality Management program is specifically tailored to meet the needs of the Sage Company by improving the quality and continuity of care as well as the ultimate cost associated with providing that care to the residents of Sabal Palms and Westchester Gardens.

TMM's four pronged approach consists of:

- 1. IDENTIFICATION**
- 2. REFERRAL**
- 3. DOCUMENTATION**
- 4. TRAINING AND COMPLIANCE**

Together these four approaches, which comprise TMM's Total Quality Management Program will improve not only the quality of care, it will enhance the quality of life for Sage's residents with limb ischemia and all of its associated problems. This program will also reduce Sage's medicolegal liability related to these problems with its attendant and often massive costs as a result of increasingly aggressive plaintiff attorneys operating in Florida's legal climate.

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TRI-MED

TOTAL QUALITY MANAGEMENT

INSPECTION → **RECOGNITION
REFERRAL
TREATMENT**

REACTIVE → **PROACTIVE**

RECORD KEEPING → **DOCUMENTATION**

DATA → **INFORMATION**

SUSCEPTIBILITY → **PROTECTION**

PROGRAM OUTLINE

Arterial occlusive disease (ASO) is a common condition in the elderly skilled nursing facility (SNF) resident population. When severe, this disease can produce critical ischemia, which may lead to skin breakdown and ulceration, often culminating in limb loss. Unfortunately, severe ASO often goes unrecognized as its signs and symptoms are often not detected by primary care physicians and/or SNF nursing personnel. Appropriate treatment is thus frequently delayed and, when rendered, may be insufficient or inappropriate to resolve the resident's acute problem. An extended period of futile wound care and progressive debility culminating in loss of limb and/or life is the unfortunate outcome in far too many cases.

Florida's legal climate places SNF's in a position of primary responsibility for adverse resident outcomes, even when the facility is not the primary determinant of care. Aggressive plaintiff's attorneys seize any opportunity to file suit against a SNF and, with the generally negative image of SNF's which has been projected in the lay press, substantial settlements have been all too common in cases that have gone to trial, even when the SNF has borne no responsibility for the adverse outcome. Loss of limb is a signal event, which often is interpreted by residents and/or family as a sign of insufficient medical care. It is frequently the precipitating factor, which leads to a negligence suit. Documentation of the bases of treatment decisions is usually lacking and this adds to the impression that less than ideal care was rendered to the resident. The result is large legal costs and inevitable increases in insurance premiums which adversely affect Sage Company's bottom line.

The TMM program of Total Quality Management is designed to improve the care of residents with lower extremity arterial occlusive disease by instituting a four-pronged program in Sage's SNF's designed to **Identify** patients at risk for complications related to lower extremity ASO, **Refer** them for appropriate diagnostic and therapeutic care and **Document** the significant aspects of their management relative to this problem. In addition, an ongoing **Training and Compliance** program will be maintained within each facility to improve the awareness of ASO management among SNF personnel and assure continued compliance with all aspects of the program.

In addition to the clear benefits and improvement in quality of life afforded to residents with these problems, the TMM program will minimize complications of ASO, including limb loss. The number of lawsuits filed will be proportionally reduced and SNF liability will be minimized in those that are filed. As an ancillary benefit, TMM will facilitate access to quality expert medical defense witnesses in ongoing and subsequent litigation. TMM will also provide a letter to be sent to each physician on the Sage facility medical staff explaining the reasons for the program and outlining its features. A summary of each aspect of the program follows.

IDENTIFICATION

TMM has developed specific criteria to identify residents at risk for critical ASO. These criteria are based on admitting diagnoses and/or diagnoses added after admission by the nursing and physician examination. It is anticipated that these criteria will identify the great majority of residents who potentially suffer from critical ischemia, symptomatic or not. Any resident with an extremity ulcer will also be evaluated for critical ASO.

Specific section of the Minimum Data Set and the complete admission history and physical examination will be reviewed by TMM medical staff within 48 hours of admission. Pre-admission screening will also be available if requested by the Sage facility. Admission total body assessment data will be included in this initial review. Sage personnel will be trained to focus on specific findings designed to increase the accuracy of detection of ASO and limb ulceration.

The foregoing data will be transmitted by facsimile to TMM within 48 hours of admission and TMM will then return a preliminary diagnosis of "Resident potentially at risk" or "Resident not at risk" for developing complications of ASO. Residents who are not found to be at risk but who have extremity ulcers on admission or who develop in-house acquired extremity ulcers will be evaluated on a regular monthly basis by TMM nursing staff on their regular visits until the lesion(s) are healed. Failure to make sufficient progress toward healing on each monthly evaluation will trigger a referral for vascular surgical evaluation.

Residents potentially at risk will be evaluated by a lower extremity noninvasive pressure examination performed by an ICAVL accredited vascular laboratory within 48 hours and the results will be transmitted via facsimile to TMM immediately upon receipt. A final determination of "Resident at risk" or "Resident not at risk" will be promptly transmitted back to the SNF.

REFERRAL

Identification of a patient potentially at risk for complications of ASO will prompt an immediate referral to a noninvasive vascular laboratory accredited in lower extremity vascular diagnosis by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL). This national organization certifies vascular laboratories after a rigorous inspection process and their seal of certification assures that the examination will be done appropriately and accurately. Meaningful data upon which to base a rational clinical decision is the result. The examination is to be completed within 72 hours of preliminary classification as "potentially at risk" and the results of the examination are to be transmitted to TMM upon receipt. This data will provide the ultimate basis upon which the final classification of "at risk" or "not at risk" will be based.

Residents at risk for critical ischemia with associated extremity lesions and those with noninvasive evidence of severe ischemia will be referred for a vascular surgical evaluation to be completed within seven days following final classification. The purpose of this examination will be to determine whether immediate revascularization is necessary. Selection of a vascular surgeon will be done in consultation with the patient's primary care physician in order to avoid disrupting his or her normal referral patterns. Some residents may have undergone a recent vascular surgery evaluation in an in-patient acute care facility within the previous thirty days and that evaluation may be sufficient.

Each vascular surgery evaluation will be reviewed by TMM upon transmittal by the facility and used as a basis for regular monthly follow up evaluation by the TMM nursing staff. Any patient failing to make sufficient progress in healing an extremity ulcer may be referred for follow up vascular laboratory and/or vascular surgery evaluations upon the recommendation of TMM staff after their regular monthly assessments. In addition, any resident with signs or symptoms suggestive of deteriorating arterial blood flow may also be referred for vascular laboratory evaluation. TMM staff will also review at least ten patient charts on a random basis at each monthly visit as a check on the adequacy of evaluation and examination by SNF personnel.

DOCUMENTATION

I. INITIAL EVALUATION

The results of all noninvasive vascular laboratory evaluation are to be placed on the resident's chart. For residents determined to be "at risk" any and all vascular surgery physician evaluations are to be placed on the chart. This evaluation will include an assessment of the severity of disease and a treatment plan. Any decision not to revascularize a patient with critical ischemia should be explained. Monthly physician evaluations by the primary care physician should be in the chart to include an assessment of any lesions present and a plan of care.

Final TMM classification will be provided to the facility for their records. Patient and/or responsible party assent to the recommended course of treatment will also be placed on the chart. The plan should be explained to the appropriate individual(s) by SNF Director of Nursing or Associate Director of Nursing and signature obtained at that time on the appropriate form. Refusal of recommended care should also be documented by signature. Samples of consent and denial forms follow this section. TMM recommends that Sage have their legal counsel review these forms before implementing their use. If the patient and/or responsible party refuse to sign any consent or denial forms, this will be documented in the chart by the DON or ADON and an unsigned copy of the appropriate form inserted in the chart.

II. FOLLOW UP EVALUATION

Monthly assessments of clinical status and wound status will be made by TMM nursing personnel. This will include recommendations for additional care, further noninvasive vascular evaluations and/or vascular surgical evaluations. Adequacy of primary physician evaluations will also be documented. Status reports and recommendations will be provided to the facility after each monthly visit. Additional consent or denial forms may be required if there has been a change in resident clinical status.

TRAINING AND COMPLIANCE

Prior to initiation of the program, TMM medical and nursing staff will conduct a mandatory in-service training program to familiarize SNF personnel with the details of the program and to improve their level of knowledge regarding the detection and management of residents with ASO and lower extremity ischemia. This program will utilize a lecture format supplemented by clinical examples. The program will be videotaped so that it can be utilized to train new personnel hired after the program is initiated. Additional in-service training will be provided as necessary.

An outline of the topics to be covered follows:

1. Definition of the problem
2. Arteriosclerosis obliterans (ASO)—clinical presentation, symptoms and physical signs
3. Extremity ulcer evaluation and care
4. Use of noninvasive vascular diagnostic evaluation
5. Revascularization options
6. Ancillary methods, including infection control
7. Question and answer session
8. In-facility rounds with nursing staff
9. Discussion of specifics of TMM program

Compliance reports will be provided monthly to the Sage facility. These will include the following data:

1. Timeliness of initial assessment and notification to TMM
2. Timeliness of vascular laboratory evaluation and notification to TMM
3. Timeliness of any required vascular surgery evaluation
4. Appropriate documentation on chart
5. Results of random surveys
6. Attending physician notes and plan of care